PHARMACY BOARD[657]

Adopted and Filed

Rule making related to collaborative pharmacy practice

The Board of Pharmacy hereby amends Chapter 39, "Expanded Practice Standards," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in 2021 Iowa Acts, Senate File 296.

State or Federal Law Implemented

This rule making implements, in whole or in part, 2021 Iowa Acts, Senate File 296.

Purpose and Summary

This amendment updates a Board rule relating to collaborative pharmacy practice agreements between pharmacists and Iowa-licensed prescribers who have independent prescribing authority. The rule making identifies the minimum required elements of such agreements.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on November 3, 2021, as **ARC 6012C**. A public hearing was held on November 24, 2021, at 10:30 a.m. in the Health Professions Board Room, 400 S.W. 8th Street, Suite H, Des Moines, Iowa, as well as via Zoom. Four individuals attended the public hearing, but none provided public comments.

The Board received three written comments. The comments recommended that the Board specifically identify physician assistants as individuals authorized to enter into collaborative pharmacy practice agreements with pharmacists; recognize a hospital's pharmacy and therapeutics committee in establishing such agreements; and remove the requirement that each pharmacist review the contents of a collaborative practice agreement, because the associated recordkeeping would be onerous for pharmacies.

The Board declined the recommendation relating to physician assistants because those practitioners do not have independent prescribing authority to delegate the activity to a pharmacist. The Board agreed with the suggestion to recognize a hospital's pharmacy and therapeutics committee in establishing collaborative practice agreements and revised the rule making accordingly. While the Board recognizes the challenges of documenting pharmacist review of such agreements, the Board believes it imperative that pharmacists review such agreements before engaging in the authorized practice and that attestation to such review need not be terribly complicated; as such, paragraph 39.13(2)"e" was revised to remove the requirement that the documentation be maintained by the pharmacy department, allowing the documentation to be maintained by a human resources department instead.

Adoption of Rule Making

This rule making was adopted by the Board on January 11, 2022.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on March 16, 2022.

The following rule-making action is adopted:

Rescind rule 657—39.13(155A) and adopt the following **new** rule in lieu thereof:

657—39.13(155A) Collaborative pharmacy practice.

39.13(1) *Definitions.* For the purpose of this rule, the following definitions shall apply:

"Collaborative pharmacy practice" means a practice of pharmacy whereby one or more pharmacists provides patient care and drug therapy management services not otherwise permitted to be performed by a pharmacist to patients under a collaborative pharmacy practice agreement with one or more practitioners which defines the nature, scope, conditions, and limitations of the patient care and drug therapy management services to be provided by the pharmacist(s) in order to ensure that a patient achieves the desired outcomes.

"Practitioner" means a physician, dentist, podiatric physician, veterinarian, optometrist, or advanced registered nurse practitioner who holds an active license to practice in Iowa.

39.13(2) *Collaborative practice agreement.*

- a. Pursuant to these rules, a pharmacist or pharmacy may engage in collaborative pharmacy practice under a collaborative pharmacy practice agreement with one or more practitioners, or as established by a health system pharmacy and therapeutics committee, to provide patient care and drug therapy management services to one or more patients.
 - b. A collaborative pharmacy practice agreement shall include:
- (1) The identification of the parties to the agreement, including the name(s) or category of the pharmacist(s), including registered pharmacist-intern(s) under the supervision of a pharmacist, who are authorized to perform delegated activities under the agreement and the name(s) or category of the practitioner(s) who are delegating activities under the agreement;
- (2) The establishment of the delegating practitioner's scope of practice authorized in the agreement and a description of the permitted activities and decisions to be performed by the pharmacist(s);
- (3) The protocol, formulary, or clinical guidelines that describe or limit the pharmacist's authority to perform the patient care or drug therapy management services and, as applicable, the drug name, class or category provided under drug therapy management;
- (4) A description of the process to monitor compliance with the agreement and clinical outcomes of patients;
 - (5) The effective date;
 - (6) A provision addressing termination of the agreement; and
- (7) The signatures of the parties to the agreement and dates of signing, unless established by a health system pharmacy and therapeutics committee.
- c. Parties to the collaborative pharmacy practice agreement shall review and revise such agreement as appropriate, but no less than every two years.

- d. Any collaborative pharmacy practice agreement shall be maintained by the pharmacist(s) or pharmacy and be available upon request or inspection.
- e. Prior to engaging in patient care or drug therapy management services under a collaborative pharmacy practice agreement, including when the agreement is updated, each pharmacist practicing under the agreement shall attest that the pharmacist has read and understands the agreement. Documentation of pharmacist attestation shall be maintained for at least two years from the attestation date and be available upon request or inspection.

[Filed 1/18/22, effective 3/16/22] [Published 2/9/22]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 2/9/22.